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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/676,052 | 09/28/2000 | Michael K. Skinner | 252/124 | 9790 |

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EXAMINER

WHISENANT, ETHAN C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1655

DATE MAILED: 11/19/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/676,052

Applicant(s)

SKINNER ET AL.

Examiner

Ethan C. Whisenant

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I (Claims 17- 20) without traverse in Paper No. 7 is acknowledged. Claims 1-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

6. Claim(s) 17-20 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. [US Patent No. 5,840,484 (1998)] in view of Seilhamer et al. [US Patent No. 5,840,484 (1998)] and/or Gao et al. (1994) and/or Fukushima et al. (FEB 1993 -Abstract only) and/or Goetzl et al. (SEP 1999 -Abstract only) and/or Haapamski et al. (MAR 1999 -Abstract only) and/or Gibbs et al. (SEP 1999 -Abstract only).

Claim 17 is drawn to an array of nucleic acid polymers immobilized on a solid support comprising at least two different nucleic acid polymers which are specific for a different gene associated with lipid metabolism, synthesis or action wherein each nucleic acid polymer is located at a predetermined position and wherein the array comprises nucleic acid polymers which are specific for less than 100 genes other than the selected genes.

Chee et al teach an array of nucleic acid polymers comprising all of the limitations recited in Claim 17 (see e.g. Claim 1) except these authors do not teach that the at least two different nucleic acid polymers should be specific genes associated with lipid metabolism, synthesis or action. However, Seilhamer et al. teach using arrays of nucleic acid polymers to study gene expression, while Gao et al. teach that genes expressed in lipid metabolism pathways play a critical role in metastasis. Fukushima et al. teach measuring the level of mRNAs associated with lipid metabolism, synthesis or action in normal, diseased, and regenerating liver. Goetzl et al. teach detecting mRNAs for Edg-1, Edg-2, Edg-3, Edg-4, Edg-5 while Haapamski et al. teach detecting mRNAs for phospholipase A2. Finally, Gibbs et al. teach detecting mRNAs for phospholipase D. In view of this prior art, and absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the array(s) taught by Chee et al. wherein at least two different nucleic acid polymers specific for genes associated with lipid metabolism, synthesis or action are present. The ordinary artisan would have been motivated to modify the array of Chee et al. in order to study the expression of genes associated with lipid metabolism, synthesis or action in the most expeditious way possible - that being the array methodology.

The examiner is of the opinion that absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to place any **known** gene (i.e. cDNA) or EST on an array in order to examine the genes expression in different tissues.

Claim 18 is drawn to an embodiment of Claim 17 wherein the at least two different nucleic acid polymers which are specific for a different gene associated with lipid metabolism, synthesis or action are selected from a defined group which includes Phospholipase A2, Phospholipase D1, and EDG 2.

As indicated above Goetzl et al. teach detecting mRNAs for Edg-1, Edg-2, Edg-3, Edg-4, Edg-5; Haapamski et al. teach detecting mRNAs for phospholipase A2. Gibbs et al. teach detecting mRNAs for phospholipase D.

Claim 19 is drawn to an embodiment of Claim 17 wherein one of the at least two different nucleic acid polymers which are specific for a different gene associated with lipid metabolism, synthesis or action are selected from a defined group which includes Phospholipase A2, Phospholipase D1, and EDG 2.

As indicated above Goetzl et al. teach detecting mRNAs for Edg-1, Edg-2, Edg-3, Edg-4, Edg-5; Haapamski et al. teach detecting mRNAs for phospholipase A2. Gibbs et al. teach detecting mRNAs for phospholipase D.

Claim 20 is drawn to an embodiment of Claim 17 wherein the nucleic acid polymers specific for the selected genes is a nucleic acid polymer comprising at least about 19 nucleotides which hybridize to a coding region of one of the selected genes.

Chee et al. teach this limitation wherein these authors teach that the probes of their array may comprise 9 to 20 nucleotides. Furthermore, where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim Objections

- 7.** **Claim(s) 21** is /are is objected to because it is dependent upon a rejected independent base claim,

CONCLUSION

- 8.** **Claim(s) 17-21** is/are rejected and/or objected to for the reason(s) set forth above.

- 9.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Art Unit is (703) 308-8724. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to

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Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to be 'E. Whisenant', with a long, sweeping horizontal line extending to the right.

ETHAN C. WHISENANT
PRIMARY EXAMINER